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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,407	01/28/2002	Hiroyuki Kagechika	P21632	1671

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EXAMINER	
FORD, JOHN M	

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 12/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/926,407	KAGECHIKA, HIROYUKI	
	Examiner	Art Unit	
	John M Ford	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1--4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1--4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 2---4 are drafted in terms of method of use.

Claims 2---4 violate 35 U.S.C. 101 and 35 U.S.C. 112, since they are drafted in terms of use. See Clinical Products vs. Brenner, 255 F. Supp. 151; 149 USPQ 475 (D.C. District Columbia 1966).

A "medicament" or "agent" is not statutory, and not a treatment of a specific disease. A medicament or "agent" does not express a real world disease. A medicament or agent is not a method or a composition.

Claim 1 is rejected under 35 U.S.C. 112, 2nd and 1st paragraph, as a result of the terms: heteroaryl, and, "substituted".

The heteroaryl rings possible is wide open to staggering possibilities.

Applicants place too much conception with the reader. The heteroaryl expression leaves open, which ones: Azines, Diazines, Triazines, Tetrazines. Where are the starting materials in the specification?

Conception of what the intended heteroaryl ring, may be, should not be left to the reader.

One needs to know exactly where, in the ring, the hetero atoms are: 1,2 or 1,4 or 1,2,4 or 1,3,4, etc., as each is a different entity, with a separate search.

One, on reading the indication of heteroaryl, applied by applicant, has no idea where the hetero atoms are in this unknown ring.

What are the heteroatoms?

Not all heteroaryl rings have been shown to be producible, as stable, at

room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language?

Heteroaryl is a whole body of art.

Researchers often spend their entire life on hetero N heterocyclic compounds without ever getting to hetero O or hetero S compounds. Many heteroaryl compounds, within the claim, have never been made.

Accordingly, claim 1 is rejected under 35 U.S.C. 112, 1st and 2nd paragraphs. What is being claimed? Where is the adequate representative exemplification in the specification?

The heteroaryl term presents a problem of lack of clear claiming, and support in the specification for the variables sought.

This rests conception with the reader.

What exactly is intended, and where is that supported in the specification?

A Markush listing of intended, conceived of, producible, heterocyclic rings is what is needed here. It is not possible to classify and search the molecule unless one knows exactly which heteroaryl ring is being claimed.

The ultimate utility here is pharmaceutical. Declarations of unexpected results are often presented in the pharmaceutical area. Applicants' breadth of heteroaryl produces many different heterocyclic rings that could easily affect results.

Applicants need to claim what they have demonstrated as a specific fact.

The heteroaryl expression in claim 1 is not acceptable, as it does not indicate, exactly, clearly, and specifically, what heteroaryl ring is being claimed. This expression

rests specific conception with the reader, and the specification does not include the source of the starting material for the rings which applicant now claims. One must be able to tell from simple reading of the claim what if does and not encompass.

Why? Because that compound claim precludes others from making, using, or selling that compound for 17/20 years. Therefore, one must know what compound for 17/20 years. Therefore, one must know what compound is being claimed.

The claims measure the invention, United Carbon Co. Vs. Binney & Smith Co., 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of claims held to this standard in Lockhead Aircraft Corp. Vs. United States, 193 U.S.P.Q. 449, "Claims measure the invention and resolution of invention must be based on what is claimed".

The CCPA in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 U.S.P.Q. 11, at 15.

Heteroaryl is too broadly stated in HAR in claim 1, see In re Wiggins, 178 U.S.P.Q. 421.

The claim cannot be completely searched, here, until we know exactly what heteroaryl means.

The USPTO only recognizes: C, N, O, S, Se or Te as atoms of a heterocyclic ring. Therefore, there is a need for applicants to indicate what they mean by heteroaryl.

Heteroaryl is not just a substituent; it is a whole body of art, larger than the rest of the molecule claimed here.

The specification serves various purposes, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

The heteroaryl term is not acceptable, as it reads on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Exactly what ring is being claimed need be set forth in the claim.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Co. vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic reasons for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim; this ground finds its basis in the second

paragraph of section 112; second is that language is so broad that it causes the claim to have a potential scope of protection beyond that which is justified by the specification disclosure; this ground stems from first the paragraph of section 112. Merits of language in claim must be tested in light of these two requirements.

The heteroaryl variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. The heteroaryl concept is so broad that it cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception should not be the role the reader. Applicants should, in return for a 17/20-year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the public) find that it works, in claim it, is not a proper basis for patentability, In re Kirk, 153 U.S.P.Q. 48 at page 53.

Note Rule 105

1.105 Completeness of examiner's action.

The examiner's action will be complete as to all matters, except that in appropriate circumstances, such as misjoinder of invention, fundamental defects in the application, and the like, the action of the examiner may be limited to such matters before further action is made. However, matters of form need not be raised by the examiner until a claim is found allowable.

We have to know what heteroaryl is being claimed, before further action can be taken.

All heteroaryl rings, within the scope claimed, cannot be undertaken.

Each heteroaryl is a different invention.

This very difficult situation is further compounded by "may be substituted".

Claim 1 is rejected under 35 U.S.C. 112, 2nd paragraph. What is intended by the "open" substituted?

The Supreme Court in 1928 in Corona vs. Dovan 1928 USSC; 1928 C.D. 253, objected to the open breadth of "substituted"; 276 U.S. 358.

The word "general" in line 1 of claim 1 renders the claim indefinite.

Searching claim 1 is all about a specific Ar.

The only way I can begin is go to page 7 of the spec for Ar being pyridine (first named invention). We do not know where the carboxylic-α R^5, or the $-N^R-$ is bonded, which changes the classification and search.

I have to assume R^2 and R^3 together is carbocyclic. This is a 371 application, Content in a 371 application is controlled by 37 CFR 1.475. In the case of multiple products (variable Ar), the first named invention is considered the elected product. In addition to the elected product, applicants are entitled to have one use of said compounds examined, therewith.

Claims 2---4 should be re-written as a proper specific method claim, and a pharmaceutical composition claim. A, specific, demonstratable, real world, utility is required. A method for the therapeutic treatment of diabetes—is suggested.

Claim 1 is rejected under 35 USC 102/103 as being unpatentable over Ozeki et al, US Patent 4,666,915.

See the abstract.

Claim 1 is rejected under 35 USC 102/103 as being unpatentable over Hoffmann et al, US Patent 3,415, 834. See col.1.

Claim 1 is rejected under 35 USC 102/103 as being unpatentable over Hoffmann et al, U.S. Patent No. 3,466,373.

See col.1.

JOHN M. FORD
PRIMARY EXAMINER
GROUP - ART UNIT 1624

Ford/tgd
December 15, 2003